DOK- docusate sodium capsule Major Pharmaceuticals

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be a signs of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

• take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over take 1 to 3 softgels daily.

<u>-</u>		
children 2 to under 12 years of age	take 1 softgel daily	
children under 2 years	ask a doctor	

Other information

- each softgel contains: sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water sorbitan, sorbitol

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Colace® Regular Strength Stool Softener**

DOK™ 100 mg

Docusate sodium

Stool Softener Laxative

For Use as a Stool Softener in Treating & Avoiding Constipation

Softgels

**This product is not manufactured or distributed bt Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by:

Major® Pharmaceuticals

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Product Label

^{*}contains one or more of these ingredients





Rev 10/17 No. 700370 This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener. ■ stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over 9 M-58 Re-Order 457 9 Major® Pharmaceuticals 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 10904 **Drug Facts** M Distributed by: 2 weeks

take only by mouth. Doses may be taken as a

single daily dose or in divided doses

take 1-3 softgels

Directions



Drug Facts (continued

Date:

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Lot No.:

Stop use and ask a doctor if signs of a serious condition.

you need to use a laxative for more than 1 week you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center

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MAJOR Stool Softener Laxative

■ each softgel contains: sodium 6 mg
■ store at 25°C (77°r); excursions permitted between 15-30°C (59-86°F)

Other information

children under 2 years

ask a doctor

children 2 to under

12

take 1 softgel

daily

12 years and over adults and children

years of age

Inactive ingredients edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol

propylene glycol*, purified water, sorbitan, sorbitol *may contain this ingredient

Questions or comments?

1-877-753-3935 Monday-Friday 9AM-5PM EST

DOK

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6457
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG) DOCUSATE SODIUM 100 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
SORBITAN (UNII: 6O92ICV9RU)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			

SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGI YCERIDES (LINII: C9H2L21V7LI)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51;S77;SCU1;D2
Contains			

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0904- 6457-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	02/28/2024		
2	NDC:0904- 6457-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	02/28/2024		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	02/28/2015	02/28/2024

Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2023 Major Pharmaceuticals